DETAILED ACTION

1. Applicant's amendments, filed on September 23, 2009, are acknowledged.

Claims 1-53 have been previously canceled.
Claim 112 has been added.

Claims 54-112 are pending.

Claims 54-69, 73, 74, 76, 77, 88-91, 94-105, and 107-111 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 6, 2009.

Claims 70-72, 75, 78-87, 92, 93, 106, newly added claim 112 are currently under consideration as they read on the originally elected invention of non-blocking antibodies that bind FcγRIIb of SEQ ID NO:2.

2. This Office Action will be in response to applicant's arguments, filed on September 23, 2009.

The rejections of record can be found in the previous Office Action, mailed on June 23, 2009.

3. Applicant's IDS, filed on September 23, 2009, is considered.

4. In view of applicant's amendment to claim 70, the prior objection to this claim has been withdrawn.

5. In view of applicant's amendment to the claims, the prior rejection under 35 U.S.C. 112, enablement against claims 70-72, 75, 78-87, 92, 93, and 106 regarding the limitation of "An antibody or fragment or derivative thereof" has been withdrawn.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 83 and 84 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 83 and 84 recite "an antibody that is a polypeptide" carrying "one or more" CDRs as part of the invention.

Applicant's arguments, submitted on September 23, 2009, have been fully considered but have not been found persuasive.

Applicant argues that the claims have been amended so that they do not recite "fragment of derivative thereof" anymore. Thus, applicant asserts the rejection should be withdrawn.

This is not found persuasive because claims 83 and 84 recite an antibody that is a polypeptide carrying one or more CDRs. As stated in prior Office Action mailed on June 23 2009, the specification does not provide sufficient guidance or working examples of an antibody that is a polypeptide carrying less than six CDRs. It is unpredictable with respect to altering amino acid sequence of an antibody variable region and maintaining the antibody function. It is well established in the art that the formation of an intact

antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope for reasons discussed in previous Office Action. As such applicant's arguments have not been found persuasive and the rejection has been maintained.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 70-72, 75, 78-87, 92, 93, 106, and newly added claim 112 are rejected under 35 U.S.C. 102(e) as being anticipated by Koenig et al. (US Patent 7,425,620) as evidenced by the CDRs location of variable light region of mAbGB3 disclosed in Figure 5 of the instant specification for reasons of record.

Applicant's arguments, filed on September 23, 2009, have been fully considered but have not been found persuasive.

Applicant argues that the anti-FcγRIIb antibody taught by Koenig et al. blocks the IgG binding site of the FcγRIIb which is different from the instant anti- FcγRIIb antibody capable of distinguishing FcγRIIb and FcγRIIa and specifically binds conformationally discriminating epitope (CDE) of FcγRIIb without blocking the IgG binding site of FcγRIIb.

Applicant further argues that claim 70 should not have been included in this rejection because claim 70 encompasses a substance that specifically binds an artificial

peptide or a polypeptide comprising CDE stabilized by circularization which is not taught by Koenig et al.

Thus, applicant asserts that the rejection should be withdrawn.

This is not found persuasive for following reasons:

In contrast to applicant's assertion that the claims are drawn to non-blocking antibody, it is noted that only claims 75 and newly added claim 112 encompass the asserted limitation of non-blocking feature. Claim 75 encompasses an antibody that does not interfere with immune complex binding to FcγRIIb or FcγRIIa. Giving the recitation of "or", any antibody that specifically binds human FcγRIIb in the natural environment of the receptor would meet claim 75 so long as the antibody does not interfere with immune complex binding to FcγRIIa. Newly added claim 112 merely recites that the antibody is non-blocking without claiming what is not blocked by the antibody. As such, the prior art anti-FcγRIIb antibody that binds FcγRIIa with lower affinity than FcγRIIb would be considered having the property of not blocking immune complex binding to FcγRIIa, especially in the absence of evidence to the contrary.

Further, as stated in the previous Office Action mailed on June 23, 2009, Koenig et al. teach a monoclonal antibody that specifically binds native human FcγRIIb which is endogenously expressed and present on surface of a cell with higher affinity than FcγRIIa (e.g. see column 9-16). Koenig et al. further teach a species of said antibody, 3H7, whose light chain variable region is 92.3% identical in amino acid sequence to the instant SEQ ID NO:5; the instant SEQ ID NO:5 shares at least the same CDR1 sequence to the prior art light chain variable region of 3H7 (see CDR1 location of the instant SEQ ID NO:5 on Figure 5 of the specification as-filed). As such, Koenig et al. also meet the limitations in claims 84 and 87, encompassing "one or more" CDRs from SEQ ID NO:5 and GB3 accoring to SEQ ID NOs: 5 and 7 or "a portion thereof having specificity", respectively.

Furthermore, in contrast to applicant's assertion that the prior art does not teach "substance" as recited in claim 70, it is noted instant claim 70 broadly encompasses a genus of any substance that specifically binds an artificial peptide or polypeptide comprising a conformationally discriminating epitope (CDE) in its native conformation. Given that the prior at teaches anti-FcγRIIb antibody that binds FcγRIIb in its native form and the FcγRIIb comprises CDE, the species of the prior art antibody meet the claimed genus of substance.

Therefore, applicant's arguments have not been found persuasive.

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Ram Shukla can be reached 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chun Dahle
Patent Examiner
January 5, 2010

/Maher M. Haddad/
Primary Examiner,
Art Unit 1644